

ARNOLD & PORTER LLP



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555 Twelfth Street, NW  
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March 27, 2007

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/554,287  
Int'l Filing Date: November 6, 2003  
Title: Method and Compounds for Identifying Anti-HIV  
Therapeutic Compounds  
Applicants: Gabriel BIRKUS *et al.*  
Atty. Docket: 18477.057

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (USPTO):

1. an Information Disclosure Statement;
2. a Form PTO-1449 (listing 144 references and supplying 130 references); and
3. a Return postcard.

Please stamp the postcard with the filing date of these documents and return it to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing matter number 18477.057. A duplicate copy of this letter is enclosed.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "DRM".

David R. Marsh (Reg. No. 41,408)  
Zhiqiang Zhao (Reg. No. L0117)  
Lisa A. Adelson (Reg. No. 51,204)

Attachments



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gabriel BIRKUS *et al.*

Group Art Unit: Not Yet Assigned

Appln. No.: 10/554,287

Examiner: Not Yet Assigned

Int'l. Filing Date: November 6, 2003

Atty. Docket: 18477.057

Title: Method and Compositions for  
Identifying Anti-HIV Therapeutic  
Compounds

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to consider the references listed on the attached Form PTO-1449.

Copies of the references are submitted herewith, except that copies of the U.S. patents and published applications listed on the attached Form PTO-1449 are not submitted herewith, in accordance with the Strategic Plan Final Rule, 69 Fed. Reg. 56481-56547 (September 21, 2004), effective October 21, 2004.

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

**CERTIFICATION AND/OR FEE**

Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)  
Zhiquiang Zhao (Reg. No. L0117)  
Lisa A. Adelson (Reg. No. 51,204)

Date: March 27, 2007

ARNOLD & PORTER LLP  
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FORM PTO-112  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

18477.057

APPLICATION NO.

10/554,287

APPLICANTS

Gabriel BIRKUS *et al.*

INT'L. FILING DATE

November 6, 2003

GROUP

Not Yet Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	REFERENCE PROVIDED*
	AA1	5,413,996	05/09/1995	Bodor	not required, per 69 Fed. Reg. 56481
	AB1	5,670,497	09/23/1997	Bold <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AC1	5,750,343	05/12/1998	Maag <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AD1	5,750,493	05/12/1998	Sommadosi <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AE1	5,874,577	02/23/1999	Chen <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AF1	5,914,332	06/22/1999	Sham <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AG1	6,072,053	06/06/2000	Vince <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AH1	6,312,662	11/06/2001	Erion <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AI1	6,319,946	11/20/2001	Hale <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AJ1	6,767,900	07/27/2004	Ubasawa <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AK1	2001/031773	10/18/2001	Camden	not required, per 69 Fed. Reg. 56481
	AL1	2002/0119443 A1	08/29/2002	Becker <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AM1	2003/109498	06/12/2003	Yuasa <i>et al.</i>	not required, per 69 Fed. Reg. 56481
	AN1	2004/0121316 A1	06/24/2004	Birkus <i>et al.</i>	not required, per 69 Fed. Reg. 56481

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	REFERENCE PROVIDED*	TRANSLATION
	AO1	0 267 050 A2	05/11/1988	Europe		Yes No
	AP1	0 441 192 A2	08/14/1991	Europe		x (abstract only) Yes No
	AQ1	0 465 297 A1	01/08/1992	Europe		Yes No
	AR1	0 531 597 A1	03/17/1993	Europe		Yes No
	AS1	0 632 048 A1	01/04/1995	Europe		Yes No
	AT1	0 786 455 A1	07/30/1997	Europe		Yes No
	AU1	0 852 233 A1	07/08/1998	Europe		Yes No
	AV1	0 919 562 A1	06/02/1999	Europe		Yes No
	AW1	1 295 879 A1	03/26/2003	Europe		Yes No

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*Copies of the listed references are either submitted herewith or were previously cited by or submitted to, the Office in a prior application. Pursuant to 37 C.F.R. § 1.97(d) and MPEP §609, the indicated reference may have been previously cited by or submitted to, the Office in a prior application, where the prior application is identified by its U.S. Application Number in this Information Disclosure Statement.

<b>FORM PTO-1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>				ATTY. DOCKET NO.		APPLICATION NO.	
				18477.057		10/554,287	
				APPLICANTS			
				Gabriel BIRKUS <i>et al.</i>			
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				November 6, 2003		Not Yet Assigned	
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	REFERENCE PROVIDED*	TRANSLATION	
	AX1	WO 88/06158	08/25/1988	PCT		x (abstract only)	Yes No
	AY1	WO 91/19721	12/26/1991	PCT			Yes No
	AZ1	WO 92/00988	01/23/1992	PCT			Yes No
	AA2	WO 92/18520	10/29/1992	PCT		x (abstract only)	Yes No
	AB2	WO 93/12123	06/24/1993	PCT			Yes No
	AC2	WO 93/24510	12/09/1993	PCT		x (Abstract only)	Yes No
	AD2	WO 96/14314	05/17/1996	PCT			Yes No
	AE2	WO 96/40156	12/19/1996	PCT			Yes No
	AF2	WO 97/15588 A1	05/01/1997	PCT			Yes No
	AG2	WO 98/04569	02/05/1998	PCT			Yes No
	AH2	WO 98/11906	03/26/1998	PCT			Yes No
	AI2	WO 99/62921	12/09/1999	PCT			Yes No
	AJ2	WO 00/04033	01/27/2000	PCT			Yes No
	AK2	WO 00/52015	08/09/2000	PCT			Yes No
	AL2	WO 01/13957 A2	03/01/2001	PCT			Yes No
	AM2	WO 01/13957 A3	03/01/2001	PCT			Yes No
	AN2	WO 01/17982 A1	03/15/2001	PCT			Yes No
	AO2	WO 01/19320 A2, A3	03/22/2001	PCT			Yes No
	AP2	WO 01/39724 A2	06/07/2001	PCT			Yes No
	AQ2	WO 01/39724 A3	10/18/2001	PCT			Yes No
	AR2	WO 01/46204 A1	06/28/2001	PCT			Yes No
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	REFERENCE PROVIDED*	TRANSLATION	
	AS2	WO 01/64693 A1	09/07/2001	PCT		x (Abstract only)	Yes No
	AT2	WO 01/96329 A1	12/20/2001	PCT		x (Abstract only)	Yes No
	AU2	WO 01/96354 A1	12/20/2001	PCT		x (Abstract only)	Yes No
	AV2	WO 02/03997 A1	01/17/2002	PCT			Yes No
	AW2	WO 02/06292 A1	01/24/2002	PCT			Yes No
	AX2	WO 02/08241 A2	01/31/2002	PCT			Yes No
	AY2	WO 02/103008 A2	12/27/2002	PCT			Yes No
	AZ2	WO 02/103008 A3	11/27/2003	PCT			Yes No
	AA3	WO 02/14344 A2	02/21/2002	PCT			Yes No
	AB3	WO 02/057425 A2	07/25/2002	PCT			Yes No
	AC3	WO 02/100415 A2, A3	12/19/2002	PCT			Yes No
	AD3	WO 03/028737 A1	04/10/2003	PCT			Yes No
	AE3	WO 03/050129 A1	06/19/2003	PCT			Yes No
	AF3	WO 03/059255 A2	07/24/2003	PCT			Yes No
	AG3	WO 03/064383 A2	08/07/2003	PCT			Yes No
	AH3	WO 03/066005 A2	08/14/2003	PCT			Yes No
	AI3	WO 03/080078 A1	10/02/2003	PCT			Yes No
	AJ3	WO 03/090690 A2	11/06/2003	PCT			Yes No
	AK3	WO 04/096234 A2	11/11/2004	PCT			Yes No
	AL3	WO 04/096818 A2	11/11/2004	PCT			Yes No
	AM3	WO 04/096818 A3	11/11/2004	PCT			Yes No
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FOREIGN PATENT DOCUMENTS							
	AN3	WO 05/011709 A1	02/10/2005	PCT			Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)						REFERENCE PROVIDED*	
	AO3	Abdel-Meguid <i>et al.</i> , "Inhibition of Human Immunodeficiency Virus-1 Protease by a C <sub>2</sub> -Symmetric Phosphinate. Synthesis and Crystallographic Analysis", <i>Biochemistry</i> , 32(31):7972-7980 (1993)					
	AP3	Allen <i>et al.</i> , "CI-1040 (PDI84352), a Targeted Signal Transduction Inhibitor of MEK (MAPKK)", <i>Seminars in Oncology</i> , 30(5, Suppl. 16):105-116 (2003)					
	AQ3	Andrade <i>et al.</i> , "HIV-Related Drug Metabolism and Cytochrome P450 Enzymes" <i>AIDS Clinical Care</i> , 12(11):91-95 (2000)					
	AR3	Ballatore <i>et al.</i> , "Synthesis and Evaluation of Novel Amidate Prodrugs of PMEA and PMPA", <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , 11:1053-1056 (2001)					
	AS3	Bantia <i>et al.</i> , "Purine Nucleoside Phosphorylase Inhibitor BCX-1777 (Immucillin-H)—A Novel Potent and Orally Active Immunosuppressive Agent", <i>International Immunopharmacology</i> , 1:1199-1210 (2001)					
	AT3	Beauchamp, <i>et al.</i> , "Guanine, Pyrazolo[3,4-d]pyrimidine, and Triazolo[4,5-d]pyrimidine(8-Azaguanine) Phosphonate Acyclic Derivatives as Inhibitors of Purine Nucleoside Phosphorylase", <i>Journal of Medicinal Chemistry</i> , 39:949-956 (1996)					
	AU3	Borhani <i>et al.</i> , "A-420983: A Potent, Orally Active Inhibitor of lck with Efficacy in a Model of Transplant Rejection", <i>Bioorganic &amp; Medicinal Chemistry Letters</i> , 14:2613-2616 (2004)					
	AV3	Bzowska <i>et al.</i> , "Purine Nucleoside Phosphorylases: Properties, Functions, and Clinical Aspects", <i>Pharmacology &amp; Therapeutics</i> , 88:349-425 (2000)					
	AW3	Chapman <i>et al.</i> , "Practical Synthesis, Separation, and Stereochemical Assignment of the PMPA Pro-Drug GS-7340", <i>Nucleosides, Nucleotides &amp; Nucleic Acids</i> , 20(4-7):621-628 (2001)					
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			REFERENCE PROVIDED*
	AX3	Charvet <i>et al.</i> , "Inhibition of Human Immunodeficiency Virus Type I Replication by Phosphonoformate- and Phosphonoacetate-2',3'-Dideoxy-3'-thiacytidine Conjugates", <i>Journal of Medicinal Chemistry</i> , 37(14):2216-2223 (1994)	
	AY3	Clark <i>et al.</i> , Abstract, "Mycophenolic Acid Analogues as Potential Agents Against West Nile Virus Infection", Institute for Antiviral Research, Utah State University	
	AZ3	Conklyn <i>et al.</i> , "The JAK3 Inhibitor CP-690550 Selectively Reduces NK and CD8+ Cell Numbers in Cynomolgus Monkey Blood Following Chronic Oral Dosing", <i>Journal of Leukocyte Biology</i> , 76:1-8 (2004)	
	AA4	De Clercq, "Chemotherapy of Human Immunodeficiency Virus (HIV) Infection: Anti-HIV Agents Targeted at Early Stages in the Virus Replicative Cycle", <i>Biomedicine and Pharmacotherapy</i> , 50(5):207-215 (1996)	
	AB4	De Clercq, "Highlights in the Development of New Antiviral Agents", <i>Mini Reviews in Medicinal Chemistry</i> , 2(2):163-175 (2002)	
	AC4	De Clercq, "New Developments in Anti-HIV Chemotherapy", <i>Current Medicinal Chemistry</i> , 8(13):1543-1572 (2001)	
	AD4	Dvořáková <i>et al.</i> , "Synthesis of 2'-Aminomethyl Derivatives of N-(2-(Phosphonomethoxy)ethyl) Nucleotide Analogues as Potential Antiviral Agents", <i>J. Med. Chem.</i> , 39(17):3263-3268 (1996)	
	AE4	Eisenberg <i>et al.</i> , "Metabolism of GS-7340, a Novel Phenyl Monophosphoramidate Intracellular Prodrug of PMPA, in Blood", <i>Nucleosides, Nucleotides &amp; Nucleic Acids</i> , 20(4-7):1091-1098 (2001)	
	AF4	Evans <i>et al.</i> , "Exploring Structure-Activity Relationships of Transition State Analogues of Human Purine Nucleoside Phosphorylase", <i>J. Med. Chem.</i> , 46(15):3412-3423 (2003)	
	AG4	Gobec <i>et al.</i> , Phosphonate Inhibitors of Antigen 85C, A Crucial Enzyme Involved in the Biosynthesis of the <i>Mycobacterium Tuberculosis</i> Cell Wall", <i>Bioorganic and Medicinal Chemistry Letters</i> , 14:3559-3562 (2004)	
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			REFERENCE PROVIDED*
	AH4	Gorin <i>et al.</i> , "A Novel Esterification Procedure Applied to Synthesis of Biologically Active Esters of Foscarnet", <i>Tetrahedron Letters</i> , 38(16):2791-2794 (1997)	
	AI4	Gumina <i>et al.</i> , "Advances in antiviral agents for Hepatitis B Virus", <i>Antiviral Chemistry &amp; Chemotherapy</i> , 12(Suppl. 1):93-117 (2001)	
	AJ4	Hakimelahi <i>et al.</i> , "Design, Synthesis, and Structure-Activity Relationship of Novel Dinucleotide Analogs as Agents Against Herpes and Human Immunodeficiency Viruses", <i>Journal of Medicinal Chemistry</i> , 38(23):4648-4659 (1995)	
	AK4	Hammond <i>et al.</i> , "Alkylglycerol Prodrugs of Phosphonoformate are Potent In Vitro Inhibitors of Nucleoside-Resistant Human Immunodeficiency Virus Type 1 and Select for Resistance Mutations that Suppress Zidovudine Resistance", <i>Antimicrobial Agents and Chemotherapy</i> , 45(6):1621-1628 (2001)	
	AL4	Hegedus <i>et al.</i> , "Synthesis of 4'-Methyl and 4'-Cyano Carbocyclic 2',3'-Didehydro Nucleoside Analogues via 1,4-Addition to Substituted Cyclopentenones", <i>J. Org. Chem.</i> , 69(24):8492-8495 (2004)	
	AM4	Herczegh <i>et al.</i> , "Osteoadsorptive Bisphosphonate Derivatives of Fluoroquinolone Antibacterials", <i>J. Med. Chem.</i> , 45:2338-2341 (2002)	
	AN4	Hirabayashi <i>et al.</i> , "Bone-Specific Drug Delivery Systems: Approaches via Chemical Modification of Bone-Seeking Agents", <i>Clinical Pharmacokinetics</i> , 42(15):1319-1330 (2003)	
	AO4	Holý <i>et al.</i> , "Synthesis of N-(2-Phosphonylmethoxyethyl Derivatives of Heterocyclic Bases", <i>Collect. Czech. Chem. Commun.</i> , 54:2190-2210 (1989)	
	AP4	International Search Report for International Application No. PCT/EP2003/012423, mailed February 11, 2005	
	AQ4	International Search Report for International Application No. PCT/US2004/035083, mailed August 5, 2005	
	AR4	International Search Report for International Application No. PCT/US2004/035084, mailed March 2, 2005	
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	AS4	International Search Report for International Application No. PCT/US2004/035085, mailed March 2, 2005	
	AT4	International Search Report for International Application No. PCT/US2004/042991, mailed June 6, 2005	
	AU4	Jain <i>et al.</i> , "Characterization of Pharmacological Efficacy of VX-148, a New, Potent Immunosuppressive Inosine 5'-Monophosphate Dehydrogenase Inhibitor", <i>Journal of Pharmacology and Experimental Therapeutics</i> , 302(3):1272-1277 (2002)	
	AV4	Karpenko <i>et al.</i> , "Synthesis and Antiherpetic Activity of Acyclovir Phosphonates", <i>Nucleosides, Nucleotides &amp; Nucleic Acids</i> , 22(3):319-328 (2003)	
	AW4	Kato <i>et al.</i> , "Enantio- and Diastereoselective Synthesis of 4' - $\alpha$ -Substituted Carbocyclic Nucleosides", <i>Tetrahedron: Asymmetry</i> , 9:911-914 (1998)	
	AX4	Kato <i>et al.</i> , "Stereoselective Synthesis of 4' - $\alpha$ -alkylcarbovir Derivatives Based on an Asymmetric Synthesis or Chemo-Enzymatic Procedure", <i>Chemical &amp; Pharmaceutical Bulletin</i> , 47(9):1256-1264 (1999)	
	AY4	Kilpatrick <i>et al.</i> , "Intravenous and Oral Pharmacokinetic Study of BCX-1777, a Novel Purine Nucleoside Phosphorylase Transition-State Inhibitor, <i>In vivo</i> Effects on Blood 2'-Deoxyguanosine in Primates", <i>International Immunopharmacology</i> , 3:541-548 (2003)	
	AZ4	Kim <i>et al.</i> , "Regiospecific and Highly Stereoselective Electrophilic Addition to Furanoid Glycals: Synthesis of Phosphonate Nucleotide Analogues with Potent Activity Against HIV", <i>J. Org. Chem.</i> , 56(8):2642-2647 (1991)	
	AA5	Kinsky <i>et al.</i> , "Inhibition of Cell Proliferation by Putative Metabolites and Non-Degradable Analogs of Methotrexate- $\gamma$ -Dimyristoylphosphatidylethanolamine", <i>Biochimica et Biophysica Acta</i> , 917(2):211-218 (1987)	
	AB5	Kinsky <i>et al.</i> , "Effect of Liposomes Sentitized with Methotrexate- $\gamma$ -Dimyristoylphosphatidylethanolamine on Cells that are Resistant to Methotrexate", <i>Biochimica et Biophysica Acta</i> , 885:129-135 (1986)	
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			REFERENCE PROVIDED*
	AC5	Kinsky <i>et al.</i> , "Circumvention of the Methotrexate Transport System by Methotrexate-Phosphatidylethanolamine Derivatives Effect of Fatty Acid Chain Length", <i>Biochimica et Biophysica Acta</i> , 921:96-103 (1987)	
	AD5	Ko <i>et al.</i> , "Efficient Synthesis of Novel Carbocyclic Nucleosides via Sequential Claisen Rearrangement and Ring-Closing Metathesis", <i>Tetrahedron Letters</i> , 43:6399-6402 (2002)	
	AE5	Kofoed <i>et al.</i> , "Regiosomers of 2',3'-Dideoxynucleosides Related to 2-(Phosphonylmethoxy)ethyl Nucleosides", <i>Bulletin de la Societe Chimique de France</i> , 134:59-65 (1997)	
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	AL5	Menéndez-Arias, "Targeting HIV: Antiretroviral Therapy and Development of Drug Resistance", <i>TRENDS in Pharmacological Sciences</i> , 23(8):381-388 (2002)	
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AM5	Ono-Nita <i>et al.</i> , "Novel Nucleoside Analogue MCC-478 (LY582563) Is Effective Against Wild-Type or Lamivudine-Resistant Hepatitis B Virus", <i>Antimicrobial Agents and Chemotherapy</i> , 46(8):2602-2605 (2002)		
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AS5	Roberts, "Development of the Route to the New Anti-AIDS drug Abacavir: A highlight of Academic/Industry Liaison", <i>IDrugs</i> , 1(8):896-899 (1998)		
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	AX5	Schultz, "Prodrugs of Biologically Active Phosphate Esters", <i>Bioorganic &amp; Medicinal Chemistry</i> , 11:885-898 (2003)	
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	AZ5	Shi <i>et al.</i> , "Plasmodium Falciparum Purine Nucleoside Phosphorylase", <i>The Journal of Biological Chemistry</i> , 279(18):18103-18106 (2004)	
	AA6	Siddiqui <i>et al.</i> , "Design and Synthesis of Lipophilic Phosphoramidate d4T-MP Prodrugs Expressing High Potency Against HIV in Cell Culture: Structural Determinants for in Vitro Activity and QSAR", <i>Journal of Medicinal Chemistry</i> , 42(20):4122-4128 (1999)	
	AB6	Sintchak <i>et al.</i> , "The Structure of Inosine 5'-Monophosphate Dehydrogenase and the Design of Novel Inhibitors" <i>Immunopharmacology</i> , 47:163-184 (2000)	
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	AM6		
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